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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1656

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,685	Applicant(s) MI ET AL.	
	Examiner Karen Cochran Carlson	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-100 is/are pending in the application.
- 4a) Of the above claim(s) 79, 82-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-78, 80, 81 and 100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2006, 2008</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's election with traverse of Group I, Claims 58-78, 80, 81, and 100 in the reply filed on November 13, 2007 is acknowledged. Applicants further elected polynucleotides encoding amino acids 454-458 of SEQ ID NO: 2 to represent the sequences listed in Claim 59a, d, e, f, g, h, i, k, l, o, p, and q. The traversal is on the ground(s) that Claim 58 does not read on a single amino acid sequence. This is not found persuasive because art was found on amino acids 454-458 of SEQ ID NO: 2 and therefore lack of unity is broken. As noted in the restriction requirement, the non-elected process claims will be rejoined when allowable subject matter is determined.

Applicants assert that they are entitled to have at least 10 sequences searched in this examination. The rule is *up to 10* nucleotide sequences, and the rule does not entitle examination of more than one sequence.

Applicants assert that they are entitled to have additional species searched if the generic claim is allowable. The restriction requirement was not drawn to an election of species but to the election of a specific sequence. The broadest claims were examined, and art found that anticipated or rendered obvious these claims and those limited to amino acids 454-458 of SEQ ID NO: 2 and the encoding polynucleotides. Thus, only SEQ ID NO: 2 and amino acids 454-458 of SEQ ID NO: 2 have been searched.

The requirement is still deemed proper and is therefore made FINAL.

Benefit of priority is to March 19, 2003.

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Note that Sp35 is known as LINGO and LINGO-1 in the prior art. See specification at page 2 line 26-27.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59-78, 80, 81, and 100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims comprise non-elected subject matter and therefore the claims do not point out or distinctly claim the subject matter which the Applicants regard as their elected invention.

In Claim 61, it is not clear if the addition of cysteines and the purification facilitating polypeptide are separate or together because there is no comma between the two.

In Claim 63, nucleic acids encode proteins, but whether the protein is cyclic or not is a post-translational event.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58, 59, 64-66, 69, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Osada et al. (2001; Assignment of 118 novel cDNAs of cynomolgus monkey brain to human chromosomes. Gene. 275: 31-37).

Osada et al. teach nucleic acid encoding LINGO-1 (Table 1, AB046639) derived from cynomolgus monkey. LINGO-1 differs from instant SEQ ID NO: 2 at Ser527Pro. Therefore, LINGO-1 amino acids 1-526 or 528-614 are fragments of SEQ ID NO: 2.

Therefore, Osada et al. teach an isolated nucleic acid encoding a fragment of SEQ ID NO: 2 (**Claim 58**), wherein the nucleic acid encodes amino acids 454-458 of SEQ ID NO: 2 (**Claim 59p**).

At page 32, left col., last sentence at para 2.2, the cDNA was placed into plasmid pME18S-FL3 (**Claim 65, 66**) and these plasmids were transformed into host cells (**Claim 69, 70**). The making of plasmids and electroporation of cells requires compositions comprising water. Therefore, Osada et al. teach a composition comprising a polynucleotide encoding amino acids 454-458 of SEQ ID NO: 2 and a pharmaceutically acceptable carrier (**Claim 64**).

Claims 58-78, 80, and 100 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al. (1998; USP 5,707,829).

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Jacobs et al. teach SEQ ID NO: 6 comprising amino acids 454-458 of instant SEQ ID NO: 2 at amino acids 65-69 of Jacobs et al. SEQ ID NO: 6. Jacobs et al. nucleotides 268-283 of SEQ ID NO: 5 encodes Jacobs et al. amino acids 65-69 of SEQ ID NO: 6.

Therefore, Jacobs et al. teach an isolated nucleic acid encoding a fragment of instant SEQ ID NO: 2 (**Claim 58**), wherein that fragment is amino acids 454-458 of SEQ ID NO: 2 (**Claim 59p**).

At Col. 6, line 21-30, Jacobs et al. teach to fuse fragments of SEQ ID NO: 6 to carrier molecules such as immunoglobulins and particularly IgFc. At Col. 7, line 27+, Jacobs et al. teach to express the protein in a form which will facilitate purification, such as with epitope tags. (**Claims 60, 61, 62**)

At Col. 6, line 17, Jacobs teach to cyclize fragments of SEQ ID NO: 6 (**Claim 63, 73**).

At Col. 6, line 31+, Jacobs et al. teach to place the polynucleotide sequence SEQ ID NO: 5 into a vector (**Claim 65, 66**) and at line 45+ teach to express the protein in suitable host cells (**Claim 69, 70, 100**). This method of placing nucleic acid into plasmids and transforming host cells with the plasmid requires compositions comprising water, for example. Therefore, Jacobs et al. teach a composition of nucleic acid SEQ ID NO: 5 in a pharmaceutically acceptable carrier (**Claim 64**). Therefore, Jacobs et al. teach isolated polypeptides comprising fragments of SEQ ID NO: 2 and comprising amino acids 454-458 of SEQ ID NO: 2 (**Claim 71, 72**). At Col. 7, the protein may be produced

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by operatively linking the encoding polynucleotide into a baculovirus/insect expression system (**Claim 67, 68**).

Pharmaceutical compositions of protein are set forth at Col. 16, line 25+ (**Claim 80**). At Col. 20, line 9, the polypeptide can be placed with co-polymers such as polyethylene glycol (**Claim 74-78**).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 58, 69, 70, 71, 72, 80, and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osada et al. (2001; Assignment of 118 novel cDNAs of cynomolgus monkey brain to human chromosomes. Gene. 275: 31-37).

The teachings of Osada et al. are set forth above. Osada et al. teach the deduced amino acid sequence of LINGO-1, which differs from instant SEQ ID NO: 2 at Ser527Pro. Therefore, LINGO-1 amino acids 1-526 or 528-614 are fragments of SEQ ID NO: 2. Osada et al. do not teach the isolated LINGO-1.

Osada et al. teach that the cDNA of Old World monkeys are highly similar to that of the human genome at the molecular level (page 32, left col., top) and that these cDNAs maybe used to isolate novel genes encoding protein in humans (Abstract; page 31). Osada et al. teach that LINGO-1 has many motifs such as the

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dyhydrogenase/reductase signature, connexin signature 1, EGF-like domain signature 2, and calcium binding EGF domain signature pattern (Table 2; F6, F17, F24, F25).

It would have been obvious for a person having ordinary skill in the art to use the host cells of Osada et al. to recombinantly produce the LINGO-1 protein comprising a fragment of SEQ ID NO: 2 and amino acids 454-458 of SEQ ID NO: 2 (**Claim 58, 71, 72**) and isolate the protein therefrom (**Claim 69, 70, 100**) because Osada et al. teach that this protein has many recognized signature motifs in humans and may further elucidate the potential of human genes and proteins. Cell culture medium and compositions used to isolate proteins comprise water. Therefore, compositions comprising polypeptides comprising fragments of SEQ ID NO: 2 or fragments comprising 454-458 of SEQ ID NO: 2 and a pharmaceutically acceptable carrier is obvious (**Claim 80**).

Claims 58, 59, 64-66, 69, 70, 71, 72, 80, and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osada et al. (2001; Assignment of 118 novel cDNAs of cynomolgus monkey brain to human chromosomes. Gene. 275: 31-37).

The teachings of Osada are set forth above in the rejections under 35 USC 102(b) and 103.

As noted in the restriction requirement, Applicants may elect a single sequence to represent all or a subset of claimed sequences. Applicants elected amino acids 454-458 of SEQ ID NO: 2 and encoding polynucleotide to represent the subset of polynucleotides and amino acids sequences of Claim 59a, d, e, f, g, h, i, k, l, o, p, and q,

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as applied to elected Group 1, Claims 58-78, 80, 81, and 100. Therefore, in accordance to Applicant's election, all of the fragments of SEQ ID NO: 2 listed in Claim 59a, d, e, f, g, h, i, k, l, o, p, and q are obvious variants of polynucleotides encoding amino acids 454-458 of SEQ ID NO: 2 and polypeptides comprising 454-458 of SEQ ID NO: 2 as applied to the teachings of Osada et al.

Claims 58-78, 80, and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. (1998; USP 5,707,829).

The teachings of Jacobs et al. are set forth above.

As noted in the restriction requirement, Applicants may elect a single sequence to represent all or a subset of claimed sequences. Applicants elected amino acids 454-458 of SEQ ID NO: 2 and encoding polynucleotide to represent the subset of polynucleotides and amino acids sequences of Claim 59a, d, e, f, g, h, i, k, l, o, p, and q, as applied to elected Group 1, Claims 58-78, 80, 81, and 100. Therefore, in accordance to Applicant's election, all of the fragments of SEQ ID NO: 2 listed in Claim 59a, d, e, f, g, h, i, k, l, o, p, and q are obvious variants of polynucleotides encoding amino acids 454-458 of SEQ ID NO: 2 and polypeptides comprising 454-458 of SEQ ID NO: 2 as applied to the teachings of Jacobs et al.

No Claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656